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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,864	07/22/2003	Dietrich Wilhelm Schacht	6102-000069/US	6414

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EXAMINER	
BUCKLEY, AUDREA	
ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,864	SCHACHT ET AL.	
	Examiner	Art Unit	
	AUDREA J. BUCKLEY	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/24/2009 has been entered. Claims 1-6 and 8-13 are pending and examined on the merits herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute a complete set of actions being applied to the instant application.

Applicant's Amendments to the claims as filed 2/15/2008 are acknowledged and remain the most recent set of claim amendments made of record. Applicant's remarks and request for continued examination submitted 9/24/2009 are acknowledged.

Withdrawn Claim Rejections

In view of Applicant's arguments presented 9/24/2009, the provisional obviousness-type double patenting rejection over 10/429,283 in view of D'Angelo is hereby withdrawn. In particular, it is the distinguishing feature of the microcapsule

diameter limitation as claimed in the instant invention which has been pointed out and is convincing.

Maintained Claim Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, and 8-13 are rejected as being unpatentable over D'Angelo et al. (US Patent 5,932,240), in view of Lauterbach (US Patent Application No. 2003/0027793 A1).

D'Angelo et al. teach a multidose transdermal drug delivery system comprising a laminate composite with a plurality of compartments, wherein each compartment is a reservoir for a unit dose of a drug active to be transdermally administered, wherein said unit doses being in the form of a multiphase composition of microspheres wherein an internal phase comprises the drug actives and adjuvants, and said internal phase is surrounded by an outer phase of film-forming polysaccharides engrafted with transdermal promoters, said microspheres beinq distributed through a diffusible matrix of said composition (abstract and reference claim 1). The patch assembly consists of a base in which the steady state dosage is contained as needed by the patient and individual

medicament reservoirs which may be activated by either a "tear-and-release" or "pull-and-release" mechanism (i.e. backing layer; col. 2, lines 56- 61). The reservoirs contain medicament which can be the same as contained in the base or various unit dosages of the base (col. 2, lines 61-67). D'Angelo et al. teach that various drugs can be delivered in unit doses, including antiparkinson drugs (col.1, lines 57 to col. 2, line 21; col. 2, line 67 to col. 3, line 8). D'Angelo et al. teach a multidose transdermal drug delivery system comprising a laminate composite of a drug- permeable membrane to be placed in contact with a patient's skin; a transfer gel layer disposed on the membrane; a permeable membrane disposed on the transfer gel layer; overlaid impervious drug enclosure means for receiving and protectively enclosing a drug active to be transdermally administered; wherein the drug enclosure means and the permeable membrane defining a plurality of compartments there between defining reservoirs for respective unit doses of the drug active; and individual activation means for releasing unit doses of the drug active form respective ones of the compartments for contacting with the patient's skin (col. 3, lines 9-23). As to claims 12 and 13, D'Angelo et al. teach reservoirs comprising microencapsulations of the drug active, wherein the drug active may be insulin encapsulated into capsules of substantially 1 to 150 microns diameter, the microencapsulations are formed of a layer of polymer encapsulating the drug active, the polymer layer having drug-penetration moieties engrafted thereon (col. 3, lines 51-57). D'Angleo et al. disclose that laminate composite forming the reservoirs for the drug actives and associated vehicles may be formed from flexible or rigid materials, including regenerated cellulose (cellophane), ABS polymer/cellulose acetate (col. 4, lines 44-56). D'Angelo et al. teach Cotran 9872 acrylate adhesive for adhering the patch to the skin (=

self-adhesive layer; col. 7, lines 2-9).). As to claims 10 and 11, D'Angelo et al. teach that useful dimensions for the patch are approximately one inch by two inches and up to about one quarter to half inch in thickness (col. 4, lines 61-63), while the size of each reservoir is determined by the volume of the unit dose to be administered (col. 4, lines 63-67). D'Angelo et al. teach that the drugs and their adjuvants are dissolved, suspended, absorbed or contained in matrices or solutions, wherein useful matrices are gels of bipolymers such as alginates, gelatins, chitin, and PVP (col. 5, lines 2-3).

Although D'Angelo et al. teach that trandermal drug delivery systems wherein various drugs, such as antiparkinsonism drugs may be included in the microreservoirs, and acrylate adhesive for adhering the patch to the skin, this reference does not teach the specific instantly claimed compound or silicone pressure adhesives (col. 1, line 57 to col. 2, line 21; and col. 7, line 2 to col. 8, lines 24-55).

Lauterbach et al. teach silicone-based transdermal therapeutic system comprising rotigotine as the active ingredient wherein it was shown that rotigotine free base form in a silicone matrix provided unexpectedly high plasma levels of rotigotine (abstract; para. 0014). Lauterbach et al. teach that said silicone-based transdermal therapeutic system must contain at least one amine resistant silicone compound as the main component, wherein the silicone compound is usually a pressure sensitive adhesive or a mixture thereof and will form a matrix in which the other components of the TTS are embedded e.g. polydimethylsiloxane (PDMS)/resin network (para. 0020). Lauterbach et al. disclose that while acrylate system is able to dissolve more drug than the silicone system, silicone in turn allows for a better release of the drug to skin (para. 0012). Lauterbach et al. teach silicone transdermal system comprising a solubilizer, including polyvinylpyrrolidone,

polypropylene glycol, ... (para. 0022). Lauterbach et al. teach that a preferred content of rotigotine per patch is in the range of 0.1 to 2 mg/square cm (para. 0027). Lauterbach et al. exemplifies a transdermal therapeutic system using a combination of silicone-type pressure sensitive adhesives, wherein rotigotine was present in free base solution (346.4 g) in ethanol. Lauterbach et al. teach a polyester release liner (SCOTCHPAK 1022). See para. 0040. Lauterbach et al. teach a backing layer that is inert with respect to the constituents of the matrix, a self-adhesive matrix layer containing an effective quantity of rotigotine or rotigotine hydrochloride and a protective film which is to be removed before use, wherein the matrix system is composed of non-aqueous polymer adhesive system, based on acrylate or silicone; and wherein said matrix is essentially free of inorganic silicate particles (page 2, para 0011).

It would have been prima facie obvious to a person of skill in the art at the time the invention was made to combine the teaching of D'Angelo et al. (US Patent 5,932,240) and Lauterbach et al. (US Patent Application Pub. No. 2003/0027793 A1) by adding rotigotine free base to the microreservoirs component of the transdermal formulation taught by D'Angelo et al. (US Patent 5,932,240) to provide multiple unit doses of rotigotine. One would have been motivated to add rotigotine free base to the transdermal delivery system to provide multiple unit doses of rotigotine because D'Angelo suggest that drugs used to treat Parkinson's disease may be included in the microreservoirs of the transdermal patch. Besides, one would appreciate the desirability of administering multiple unit doses, wherein a given dose of a drug is delivered transdermally in multiple doses instead of a single large dose, as this would allow smaller doses of the drug to be administered to a patient per unit of time, which would result in less dose-related side

effects. Further, it would have obvious to a person of skill in the art to add a silicone pressure adhesive as taught by Lauterbach et al. to the adhesive component of the transdermal formulation for additive adhesive effect because Lauterkach et al. suggest that mixtures of pressure sensitive adhesives can be used in transdermal formulations and both Lauterbach et al. and D'Angelo et al. teach transdermal formulations. In view of the fact that the cited art teaches all the instant claimed limitations, the trandermal drug delivery system encompassed by the prior art is capable of performing the intended function (e.g. substantially impermeable to the protonated form of rotigotine). It is noted that D'Angelo et al. teach PVP, which overlaps with the instantly claimed crystallization inhibitor (claims 8 and 9). Hence, one would reasonably expect that the size of the microreservoirs containing PVP as taught by the cited art would be similar in size to the instantly claimed microreservoirs (claims 10-13). Besides, D'Angelo et al. teach that the size of the microreservoirs can be manipulated depending on the volume of the dose of drug that is intended to be delivered by the transdermal drug delivery system. It is the examiner's position that it would have been within the scope of skill and knowledge of an artisan skilled in the art to manipulate the size of the microreservoirs, including the maximum diameter, and the thickness/surface area of the matrix because this is routine in the pharmaceutical art.

Thus, it would have been obvious to a person of skill in the art at the time the invention was made to create the instant claimed invention with reasonable predictability.

Nonstatutory Obviousness-Type Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees.

A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, and 8-13 are also rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending US Patent Application No. 10/627,990 (Appl. '990) claims 1-13, in view of D'Angelo et al. (US Patent 5,932,240) and Lauterbach.

In particular, reference claim 1 is directed towards a transdermal delivery system (TDS) comprising a backing layer, a self-adhesive matrix containing an amine functional drug, and a protective foil or sheet to be removed prior to use, wherein the self-adhesive matrix comprises a solid or semisolid semi-permeable polymer. Unlike the instant claims, the reference claims are not directed to transdermal drug delivery systems comprising rotigotine in microreservoirs. The above discussion of D'Angelo et al. is incorporated by reference. Despite the difference between the instant claims and the reference claims, it would have been obvious to a person of skill in the art at the time the invention was made

to use any suitable drug, including rotigotine modify the reference transdermal drug delivery system in order to increase the duration of maintaining therapeutically effective.

Thus, instant claims 1-6 are deemed obvious variants of the limitations of claims 1-13 of Appl. '990, in view of D'Angelo et al. and Lauterbach et al.

This is a provisional obviousness-type double patenting rejection because the conflicting claims of the copending applications have not in fact been patented.

Response to Arguments

It is noted that Applicant re-iterates that Lauterbach is not statutory prior art against the instant invention. The 102(e) date as previously applied is maintained.

As to the application of the cited references, Applicant traverses the rejection on the grounds that not all claim limitations (microreservoirs within a self-adhesive matrix and microreservoir maximum diameter) are taught in the cited art. Applicant argues against the application of D'Angelo since D'Angelo is said to teach away from a self-adhesive matrix containing microreservoirs of the specified size. Further, Applicant asserts that there is no reason to combine the cited references and that no reasonable expectation for subsequent success exists and that the office action of 6/24/2009 relies on improper hindsight reconstruction.

While Applicant's traversal arguments appear to be sound, it is noted that the claim language does not limit the scope of the invention as presented in the arguments of 9/24/2009. For example, the Cotran 9710 acrylate adhesive in the invention of D'Angelo does contain the active agent (see page 3 of 14, reply of 9/24/2009) as required by instant claim 1. Further, Applicant suggests that D'Angelo does not disclose microreservoirs

within a self-adhesive matrix since the adhesive and drug portions of the D'Angelo's assembly are separate. However, it is noted that D'Angelo teaches a permeable layer of polyethylene, an acrylate adhesive, and a permeating active agent (over which rotigotine is obvious for reasons previously stated) in a device which is to be applied directly to the surface of the skin. It is noted that the microreservoirs are situated within the structure of the matrix (see D'Angelo Figure 2) as required by instant claim 1.

As to Applicant's position that D'Angelo teaches away from the specified size of microreservoirs, MPEP 2123 (II) addresses the validity of a rejection over the prior art's broad disclosure instead of preferred embodiments as follows:

> "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

In addition, it is noted that both D'Angelo and the skilled artisan would have found the adjustment of microcapsule size and polymer permeability to have been obvious and routine procedures in order to optimize the benefits of the active agent while minimizing the undesired side effects such as skin irritation or uncontrolled or irregular active agent flux from the patch to the patient; it is noted that no evidence for this routine optimization procedure changing the principle of operation has been presented as argued on page 8 of 14 of the response of 9/24/2009. In other words, routine optimization procedure lacks patentability where the elements of the invention are known in the art; see MPEP 2144.05. As shown in the maintained rejection of the claims above and as presented in MPEP 2144.06,

> "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)).

Therefore, prima facie obviousness is maintained for the reasons set forth in the maintained rejection re-iterated above, and any combining of references relies on the skill of the artisan and not improper hindsight reconstruction. That is, implementation of a rotigotine active capable of flow from a self-adhesive matrix to the surface of the skin where the delivery device comprises a backing layer and where the self-adhesive matrix has been optimized to release the active agent as desired for effective delivery would have been prima facie obvious over the prior teachings of the function of rotigotine as well as the prior teachings of analogous transdermal delivery devices. Applicant argues that the intended purpose and principle of operation of D'Angelo are modified when the microcapsule size is altered; however, D'Angelo teaches reservoirs comprising microencapsulations of the drug active such as insulin encapsulated into capsules of substantially 1 to 150 microns in diameter (see column 3, lines 51-55), for example. In reducing the diameter of the encapuslations, if the reservoir did not maintain the transdermal patch so that it could adhere, the invention of D'Angelo would not be maintained, however it has not been shown that the cited combination of references would result in this undesired change, despite Applicant's arguments on page 10 of 14 in the reply of 9/24/2009. The obviousness rejections of the combination of D'Angelo and Lauterbach references with the ordinary skill of one in the art at the time the invention was made are maintained as articulated above in the maintained rejection of the claims.

As to the nonstatutory obviousness-type double patenting rejection of claims 1-6 and 8-13 over claims 1-13 of copending U.S. Patent Application No. 10/627,990 in view of D'Angelo et al. and Lauterbach, the rejection is maintained as the subject matter in the instant application is not in condition for allowance at this time. See MPEP 804(I)(B)(1).

Conclusion

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AUDREA J. BUCKLEY whose telephone number is (571)270-1336. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AJB/

/David J Blanchard/
Primary Examiner, Art Unit 1643